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06/27/2008

Jens Richter

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EXAMINER

PLIONIS, NICHOLAS J

ART UNIT

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3733

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/594,854	Applicant(s) RICHTER ET AL.	
	Examiner NICHOLAS PLIONIS	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-45 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 24-45 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 September 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/09/08</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Oath/Declaration

1. In the oath/declaration filed on 06/27/2008, a claim of foreign priority was made to PCT/IB2005/000826, from which the present application is a 371 national stage application (see Specification, paragraph [0001]). It is inconsistent for the above-noted PCT application to support both a claim of foreign priority and a 371 national stage application. A new oath/declaration is required in which there is no claim of foreign priority to PCT/IB2005/000826.

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 3b, 3c, 9, 12, 13. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the

Art Unit: 3733

retaining member formed as a cover in claim 37, and the screw nipple in claim 39 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

4. The disclosure is objected to because of the following informalities:

In paragraph [0014], “cumberson” should be “cumbersome” and “patent” should be “patient”.

In paragraph [0016], the second sentence is incomplete.

Appropriate correction is required. Applicant's assistance is requested in reviewing the specification to ensure all spelling and grammatical errors are addressed.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. **Claims 24, 40, and 45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

Claims 24 and 45 recite "a plurality of connecting elements" and later recite that "at least one control element being coordinated with a connecting element." It is unclear whether the latter "a connecting element" can be one of the earlier recited "plurality of connecting elements" or whether it excludes these earlier recited connecting elements. Appropriate correction is required. For the purpose of examination, the former possibility is assumed.

Claim 40 recites "holding the bone distally." There is insufficient antecedent basis for "the bone."

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 3733

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 24-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Liang Q-Y (cited by applicant on IDS filed 12/9/2008).

Regarding **claim 24**, Liang Q-Y discloses an external fixator for osteosynthesis, comprising: an external retaining member (2) configured and dimensioned for bridging separated bone segments (see Fig. 1-B); a plurality of connecting elements (1) configured and adapted for applying a clamping force to the separated bone segments (see page 84), each connecting element having a first end and a second contact end, the first end configured and adapted for attachment to the retaining member and the second contact end configured and adapted for surface attachment to one of the separated bone segments without penetrating the bone segment (see Fig. 1-b); and a plurality of control elements (screws on fixation devices, see page 84) configured and adapted for varying the clamping pressure applied by the connecting elements, at least one control element being coordinated with a connecting element and supported in the retaining member (see page 84 and Fig. 1-B).

Regarding **claim 25**, Liang Q-Y discloses wherein the contact ends of the connecting elements (1) are spoon-shaped (See Fig. 1-B).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been

Art Unit: 3733

obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Liang Q-Y, as applied to claims 24-25 above, in view of U.S. Patent No. 4,759,769 (Hedman) and U.S. Patent No. 6,142,862 (Dalgord).

The disclosure of Liang Q-Y has been previously discussed above.

Regarding **claim 26**, Liang Q-Y fails to explicitly disclose wherein the contact ends are beveled and toothed.

However, Hedman discloses the used of a teeth on surfaces contacting bone (see col. 6, lines 23-29). It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to make the contact ends of the connecting elements of Liang Q-Y toothed because, as suggested by Hedman, this would facilitate the ability of the contact ends to securely grip the bone surface (see Hedman, col. 6, lines 23-29). Additionally, Dalgord discloses beveled teeth (see col. 12, lines 18-21). It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to make the toothed surface of Liang Q-y in view of Hedman beveled because, as suggested by Dalgord, beveling more evenly distributes the gripping ability of the toothed surface (see Dalgord, col. 12, lines 18-21).

13. Claims 27, 30-32, 34, 38, 40-42, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liang Q-Y, as applied to claims 24-25 above, in view of European Patent Application Publication No. 592960 A2 (Green).

The disclosure of Liang Q-Y has been previously discussed above.

Regarding **claim 27**, Liang Q-Y fails to explicitly disclose a counter-holder, the counter-holder connected to the retaining member and including at least one flexible loop of sufficient length to wrap around a medial and lateral surface of at least one bone segment.

However, Green discloses a counter holder (12) capable of being connected to a retaining member and including at least one flexible loops of sufficient length to wrap around a medial and lateral surface of at least one bone

Art Unit: 3733

segment (see Fig. 6). It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to connect the counter-holder of Green to the retaining member of Liang Q-Y in order to provide a more secure connection of the connecting elements to adjacent bone surfaces. Further, it would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to modify the size of the counter-holder of Green such that it is compatible with the external fixator of Liang Q-Y because a change in size of a component of a device is generally recognized as being within the level of ordinary skill in the art. See *In re Rose*, 105 USPQ 237 (CCPA 1955).

Regarding **claims 30-31**, Liang Q-Y discloses U-shaped connecting elements (1) (See Fig. 1-B), and Green discloses a counter-holder (12) with a loop such that, when added to the fixator of Liang Q-Y as disclosed above, is coordinated with the two connecting elements by wrapping around them while wrapping around the fractured bone segments such that the counter-holder loop is partially supported by the connecting elements (see Fig. 6). Additionally, it would have been prima facie obvious to a person of ordinary skill in the art to locate the counter-holder of Green in the fixator of Liang Q-Y such that it wraps around the connecting elements since it has been held that relocation of parts of an invention involves only routine skill in the art. See *In re Japikse*, 86 USPQ 70 (CCPA 1950).

Regarding **claim 32**, Liang Q-Y discloses tubular connecting elements (1) (see Fig. 1-B), and, the loop of Green located as described above regarding **claims 30-31** winds through one connecting element on one bone part and

Art Unit: 3733

another connecting element on another bone part (see Green, Fig. 6 and Liang Q-Y, Fig. 1-B).

Regarding **claim 34**, Liang Q-Y discloses screws that facilitate the fixation of a component to the retaining member (see page 84). It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to use these screws or additional screws to also facilitate fixation of the loop of the counter-holder of Green to the retaining member of Liang Q-Y because such a modification merely involves a known prior art device performing a known function in a similar way.

Regarding **claim 38**, the loop of Green, located as described above regarding **claim 34**, is held in an adjustable clamping mechanism (2) of Liang Q-Y (see Liang Q-Y, page 84).

Regarding **claim 40**, Liang Q-Y discloses a method for osteosynthesis using an external fixator, comprising: attaching connecting elements (1) to a bone surface, the connecting elements having contact ends which are supported on the bone surface without penetrating the bone surface (see Fig. 1-B); connecting the connecting elements to an external retaining member (2) by means of retaining ends which are held in the retaining member (see Fig. 1-B and page 84); and exerting a lateral clamping pressure directed towards the sagittal plane with the connecting elements (see page 84). Further, the counter-holder (12) of Green, as described above regarding **claims 30-31** and **34**, distally holds the connecting elements against the bone distally in the direction of the retaining member, the counter-holder comprising at least one flexible loop which

Art Unit: 3733

wraps around a medial and lateral surface of the bone (see Fig. 6) and which can be fixed to the retaining member.

Regarding **claim 41**, Liang Q-Y discloses a control-element (screws on fixation devices, see page 84) located in the retaining member (2) coordinates the variation of the clamping pressure with each connecting element (see page 84). Further, when the counter-holder (12) of Green is located as described above regarding **claims 30-31** and **34**, the control-element would also vary the clamping pressure of each loop.

Regarding **claim 42**, when the counter-holder (12) of Green is located as described above regarding **claims 30-31** and **34**, Liang Q-Y in view of Green further discloses wherein each loop is supported on and led to at least two connecting elements.

Regarding **claim 45**, Liang Q-Y discloses an external fixator for osteosynthesis, comprising: an external retaining member (2) configured and dimensioned for bridging separated bone segments (see Fig. 1-B); a plurality of connecting elements (1) configured and adapted for applying a clamping force to the separated bone segments (see page 84), each connecting element having a first end and a second contact end, the first end configured and adapted for attachment to the retaining member and the second contact end configured and adapted for surface attachment to one of the separated bone segments without penetrating the bone segment (see Fig. 1-b); and a plurality of control elements (screws on fixation devices, see page 84) configured and adapted for varying the clamping pressure applied by the connecting elements, at least one control

Art Unit: 3733

element being coordinated with a connecting element and supported in the retaining member (see page 84 and Fig. 1-B). Green discloses a flexible loop that, combined with the fixator of Liang Q-Y as described in **claims 27 and 30-31**, is connected to the retaining member and configured and adapted for exerting control tension on the connecting elements of sufficient length to wrap around a medial and lateral surface of at least one bone segment.

14. Claims 28-29 and 42-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liang Q-Y in view of Green, as applied to claims 27, 30-32, 34, 38, 40-42, and 45 above, in view of U.S. Patent No. 5,062,844 (Jamison).

The disclosure of Liang Q-Y in view of Green has been previously discussed above.

Regarding **claims 28-29 and 42-43**, Liang Q-Y in view of Green fails to explicitly disclose components composed of x-ray transparent material, such as carbon or carbon-reinforced materials.

However, Jamison discloses making external fixation device components made of carbon-reinforced materials such that they are radiolucent (see col. 5, lines 44-48). It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to make the components of the fixator of Liang Q-Y in view of Green of a radiolucent carbon-reinforced materials because, as suggested by Jamison, radiolucency is desirable (see Jamison, col. 2, lines 37-41) and allow key areas needed to be viewed during an X-ray, such as a fracture site, to be free of obstruction.

Art Unit: 3733

15. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Liang Q-Y, as applied to claims 24-25 above, in view of U.S. Patent No. 4,643,177 (Sheppard).

The disclosure of Liang Q-Y has been previously discussed above.

Regarding **claim 33**, Liang Q-Y fails to explicitly disclose a lateral orifice a distance away from the contact end.

However, Sheppard discloses a retaining member/clamp include set screws threaded through orifices with support rods running through the retaining member (see col. 7, lines 19-23). It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to include a lateral orifice at a distance away from the contact end in order to connect the connecting elements to the external retaining member, as suggested by Sheppard (see col. 7, lines 19-23).

16. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Liang Q-Y, as applied to claims 24-25 above, in view of U.S. Patent No. 5,015,248 (Burstein).

The disclosure of Liang Q-Y has been previously discussed above.

Regarding **claim 35**, Liang Q-Y discloses wherein the control elements (1) include screws that laterally contact at least one connecting element (see page 84); however, Liang Q-Y does not explicitly disclose wherein the screws pivot relative to the retaining member.

However, Burstein discloses pivotable clamping screws in a fixation device (see col. 5, lines 4-11). It would have been prima facie obvious to a

Art Unit: 3733

person of ordinary skill in the art at the time of the invention to make the screws of Liang Q-Y pivotable relative to the retaining member in order to permit flexibility in the placement of the connecting elements, as suggested by Burstein (see Burstein, col. 5, lines 4-11).

17. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Liang Q-Y, as applied to claims 24-25 above, in view of U.S. Patent No. 3,863,640 (Haverstock).

The disclosure of Liang Q-Y has been previously discussed above.

Regarding **claim 36**, Liang Q-Y does not explicitly disclose a skin closure zip system located in a region of the connecting elements.

However, Haverstock discloses a skin closure zip system (see col. 1, lines 39-45). It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to include the skin closure zip system of Haverstock in the region of the connecting elements where there is a skin incision with the fixator of Liang Q-Y because, as suggested by Haverstock, such a system improves the condition of skin in the incision area and reduces the possibility of formation of scar tissue (see Haverstock, col. 1, lines 39-45).

18. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Liang Q-Y, as applied to claims 24-25 above, in view of U.S. Patent No. 5,545,162 (Huebner).

The disclosure of Liang Q-Y has been previously discussed above.

Regarding **claim 37**, Liang Q-Y does not explicitly disclose a retaining member forms a cover forming a completely self-contained system.

However, Huebner discloses a fixator including an enveloping cover (see col. 4, lines 45-47). It would have been prima facie obvious to a person of ordinary skill in the art to include the cover of Huebner in the fixator of Liang Q-Y because, as suggested by Huebner, such a cover is more “cosmetically acceptable” (see Huebner, col. 4, lines 45-47).

19. Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Liang Q-Y in view of Green, as applied to claims 27, 30-32, 34, 38, 40-42, and 45 above, in view of U.S. Patent No. 3,871,088 (Leitner).

The disclosure of Liang Q-Y in view of Green has been previously discussed above.

Regarding **claim 39**, Liang Q-Y in view of Green fails to explicitly disclose a clamping mechanism comprising a screw nipple of the Bowden cable type.

However, Leitner discloses a clamping mechanism comprising a screw nipple of the Bowden cable type (see col. 1, lines 3-14). It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to modify the clamping mechanism of Liang Q-Y in view of Green as suggested by Leitner because such a modification merely applies a known device from a similar clamp to the fixator of Liang Q-Y in view of Green.

Conclusion

20. Any inquiry concerning this communication should be directed to NICHOLAS PLIONIS at telephone number (571) 270-3027. The examiner can normally be reached on Monday through Friday, 9:00 a.m. through 5:00 p.m.

Art Unit: 3733

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert, can be reached at telephone number (571) 272-4719.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://portal.uspto.gov/external/portal>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/NICHOLAS PLIONIS/
Examiner, Art Unit 3733
/Eduardo C. Robert/
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